



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Bureau of Health Care Safety and Quality
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Circular Letter: DHCQ 12-5-562

TO: Out-of-Hospital Dialysis Unit Administrators
Acute Care Hospital CEOs

FROM: Madeleine Biondolillo, MD *MB*
Director, Bureau of Health Care Quality and Safety

CC: Jenny Kitsen, End Stage Renal Disease Network of New England
Anuj Goel, Massachusetts Hospital Association

DATE: May 7, 2012

RE: Clarification of Out-of-Hospital Dialysis Unit Regulations

The purpose of this circular letter is to clarify and provide guidance on the following provisions regarding chronic maintenance dialysis patients:

- The requirement that patients receive a prior evaluation and initiation of dialysis "in" an affiliated hospital [105 CMR 145.400(A)]; and,
- Whether acute dialysis patients may be treated at an out-of-hospital dialysis unit [105 CMR 145.010(A) AND 105 CMR 145.010(B)].

I. Initiation of Treatment "in" a Hospital

The out-of-hospital dialysis unit regulation at 105 CMR 145.400(A) requires patients beginning chronic maintenance dialysis to be evaluated and stabilized "in" a hospital before being admitted to an out-of-hospital dialysis unit. This provision states:

105 CMR 145.400(A): ADMISSION POLICIES AND PROCEDURES

A patient beginning chronic maintenance dialysis shall be admitted to the unit only after a period of prior evaluation and initiation of dialysis in an affiliated hospital which has a chronic dialysis service, or an acute service capable of performing diagnostic studies and completing stabilization of the patient for chronic dialysis, and which agrees to accept the patient for in-patient care and other services as needed. The period of evaluation shall include consideration of what is the most appropriate mode of treatment for the patient and whether the patient can be maintained on self-dialysis or home dialysis. (Emphasis added)

The Department has received inquiries regarding the application of this requirement. The intent of the reference in the regulation regarding "in an affiliated hospital" does not mean that the required period of prior evaluation and initiation of the patient's dialysis must be completed as an inpatient, rather the patient's evaluation and initiation of dialysis may be completed "at" an affiliated hospital that has a chronic dialysis service, or an acute service capable of performing diagnostic studies and completing stabilization of the patient for chronic dialysis.

The Department has also received inquiries from out-of-hospital dialysis unit medical directors requesting a waiver of the above referenced requirement, to allow for the initiation of dialysis at an out-of-hospital dialysis unit for select patients who have been assessed and determined to be clinically appropriate for the setting by the referring and receiving physician/nephrologist. The intent of this requirement is to ensure that each patient referred for treatment at an out-of-hospital dialysis unit is assessed and determined to be stable prior to acceptance for treatment at an out-of-hospital dialysis unit. Therefore, the Department has established the following minimum criteria in order for out-of-hospital dialysis units to provide initial dialysis treatments to select patients who have been evaluated and determined to be stable by their attending physicians/nephrologists.

Provided the following conditions are met, an out-of-hospital dialysis provider will not need to seek a waiver of **105 CMR 145.400(A)** in order to accept patients for initiation of dialysis without a period of prior evaluation and initiation of dialysis at an affiliated hospital.

The decision to admit a patient to an out-of-hospital dialysis unit, and the determination that the appropriate staff, services and resources are available at the out-of-hospital dialysis unit, remain with the clinical staff of the transferring and receiving entities. Appropriate medical and nursing staff from each entity, as applicable, must confer and agree that the admission of the patient to an out-of-hospital dialysis unit is appropriate. This determination should be made after an assessment of the patient's needs and anticipated course of treatment, development of a plan of care, confirmation that the level of services available at the out-of-hospital dialysis unit can meet the needs of the patient, and completion of appropriate discharge planning to ensure continuity of care. Specifically, the out-of-hospital dialysis unit must ensure that:

- Written policies and procedures are developed and implemented that outline the facility's ability and process to provide treatment to such patients.
- Written admission criteria include identification of patients whose conditions would not allow treatment to be safely initiated in a non-hospital setting.
- Patients are admitted to the facility for initial dialysis treatment only after an evaluation and written determination of medical stability and assurance of appropriate care transitions by the patient's attending physician/nephrologist and a physician/nephrologist in the receiving out-of-hospital dialysis unit.
- The nephrologist prescribing dialysis must provide written documentation to the dialysis unit including information such as a brief patient history and physical examination report, a current medication list, a hospital discharge summary where applicable, and an initial assessment of the patient's dialysis needs.
- Treatment objectives must be reviewed with the out-of-hospital dialysis unit medical director prior to accepting the patient for admission to ensure appropriate care transitions.
- All facilities must monitor the appropriateness of initiation of treatment in the out-of-hospital setting through quality assurance activities, and must report any significant adverse outcomes to the Department of Public Health, Division of Health Care Quality, Intake Unit, at the address on Page 1, or by calling 1-800-462-5540 or 617-753-8150.

II. Acute Dialysis Treatment

The regulation at 105 CMR 145.000, and specifically 145.010(A) and 145.010(B), restricts provision of "acute dialysis" in an out-of hospital dialysis unit.

105 CMR 145.010(A): PROCEDURES PERMITTED IN AN OUT-OF-HOSPITAL DIALYSIS UNIT

The unit shall provide chronic maintenance dialysis on the premises as set forth in 105 CMR 145.050 through 145.980 and also if permitted under the terms of its license, a home dialysis program as set forth in 105 CMR 145.800 through 145.850.

105 CMR 145.010(B): PROCEDURES NOT PERMITTED IN AN OUT-OF-HOSPITAL DIALYSIS UNIT

No unit shall provide **acute dialysis** or any other service which under 105 CMR 130.000 may be provided only at a hospital. Nor shall any unit engage in any activity which is permitted only at long-term care facilities or duties under 105 CMR 150.000. (Emphasis added.)

The Department has received requests for clarification of these regulatory citations with regard to the post-acute phase of a patient's dialysis treatment. According to 105 CMR 145.010(B), a patient who requires acute dialysis may not receive initial dialysis treatments in an out-of-hospital dialysis unit; however, after a period of prior initiation of dialysis and evaluation as an in-patient in a hospital which has performed diagnostic studies and completed stabilization of the patient, and the most appropriate mode of treatment for the patient has been determined based on the clinical decisions of the attending nephrologist and the receiving physician, the patient may be accepted for on-going treatment at an out-of-hospital dialysis unit.

The diagram below is provided to summarize the above-noted requirements:

HOSPITAL-BASED DIALYSIS TREATMENT VERSUS OUT-OF-HOSPITAL DIALYSIS TREATMENT

<u>Initial Dialysis Treatment</u>	<u>Start in in-patient setting</u>	<u>Start at out-of-hospital dialysis unit</u>	<u>Continue short term dialysis in out-of hospital dialysis unit</u>
<u>Acute Patients</u>	Yes, in accordance with 145.010(B)	No, in accordance with 145.010(B)	Yes, if clinically appropriate and in accordance with guidelines listed above
<u>Chronic Patients</u>	Yes, if clinically appropriate , and in accordance with 145.400(A)	Yes, if clinically appropriate and in accordance with guidelines listed above	Not applicable

If you have any questions, please email Paul.Dinatale@state.ma.us or Gail.Palmeri@state.ma.us or call 617-753-8000.

We request that you forward this circular letter at a minimum to the following staff at your facility:
Chief Medical Officer, Director of Dialysis Unit, Chief Nursing Officer and QA Director/Risk Manager